IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

EDITH A. HARRIS, Plaintiff, vs. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	4:21-CV-3013
JUDY COHEN, Plaintiff, vs. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	4:21-CV-3014
CONSTANCE SUNDELL, Plaintiff, vs. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	8:21-CV-32

MEMORANDUM AND ORDER

The plaintiffs have filed essentially identical complaints alleging claims of (1) strict liability for the defendant's failure to warn, (2) negligence, (3)

fraudulent misrepresentation, and (4) negligent misrepresentation in connection with the defendant's testing, marketing, promotion, labeling and distribution of its prescription medication Beovu. The defendant has moved for dismissal pursuant to Fed. R. Civ. P. 12(b)(6) arguing that the plaintiffs have failed to state claims upon which relief can be granted. For the reasons that follow, the Court will deny the defendant's motion.

I. STANDARD OF REVIEW

To survive a Rule 12(b)(6) motion to dismiss, a complaint must set forth a short and plain statement of the claim showing that the pleader is entitled to relief. Fed. R. Civ. P. 8(a)(2). This standard does not require detailed factual allegations, but it demands more than an unadorned accusation. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The complaint must provide more than labels and conclusions; and a formulaic recitation of the elements of a cause of action will not suffice. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

A complaint must also contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face. *Iqbal*, 556 U.S. at 678. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.* Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not shown—that the pleader is entitled to relief. *Id.* at 679.

In assessing a motion to dismiss, a court must take all the factual allegations in the complaint as true, but is not bound to accept as true a legal conclusion couched as a factual allegation. *Twombly*, 550 U.S. at 555. The facts alleged must raise a reasonable expectation that discovery will reveal evidence to substantiate the necessary elements of the plaintiff's claim. *See id.* at 545. The court must assume the truth of the plaintiff's factual allegations, and a

well-pleaded complaint may proceed, even if it strikes a savvy judge that actual proof of those facts is improbable, and that recovery is very remote and unlikely. *Id.* at 556.

A motion to dismiss under Rule 12(b)(6) tests only the sufficiency of the allegations in the complaint, not the sufficiency of the evidence alleged in support of those allegations. *Stamm v. Cty. of Cheyenne, Neb.*, 326 F. Supp. 3d 832, 847 (D. Neb. 2018); *Harrington v. Hall Cty. Bd. of Supervisors*, No. 4:15-CV-3052, 2016 WL 1274534, at *4 (D. Neb. Mar. 31, 2016).

II. BACKGROUND

The defendant, Novartis Pharmaceuticals, is a subsidiary of Novartis AG, and is a Delaware corporation with its principal place of business in East Hanover, New Jersey. *See, e.g.,* filing 30 at 2.[1] The drug brolucizumab is marketed by the defendant under the registered trademark Beovu. Brolucizumab is a human vascular endothelial growth factor inhibitor, and is indicated for the treatment of neovascular (wet) age-related macular degeneration in adults. *See, e.g.,* filing 30 at 4. The defendant assumed ownership and all future marketing rights to Beovu in September 2009 when it acquired Alcon, Inc. *See, e.g.,* filing 30 at 5.

The defendant's biologics license application for Beovu was accepted by the United States Food and Drug Administration (FDA) on April 15, 2019. *See, e.g.,* filing 30 at 5. On October 7, 2019, Beovu received FDA approval. The plaintiffs alleged that at all relevant times, the defendant was engaged in designing, developing, manufacturing, testing, packaging, marketing, distributing, labeling, and selling Beovu, as well as in control of its

[1] For convenience, except where noted, the Court will cite only to the filings in *Sundell*, case no. 8:21-cv-32, when discussing the plaintiffs' common allegations and arguments.

investigational new drug application and biologics license application. *See, e.g.*, filing 30 at 2.

Beovu is administered by an intravitreal injection, and treats age-related macular degeneration by suppressing the growth of abnormal blood vessels and reducing the potential for fluid leakage into the retina. *See, e.g.*, filing 30 at 6. Beuvo is the third anti-vascular endothelial growth factor inhibitor drug approved by the FDA for treatment of age-related macular degeneration. The plaintiffs alleged that retinal vasculitis and retinal vascular occlusion have been widely reported in patients treated with Beovu, but are not considered to be risks associated with other anti-vascular endothelial growth factor inhibitor drugs. *See, e.g.*, filing 30 at 7.

Retinal vasculitis is an inflammation of the vessels of the retina, which typically results in decreased vision. Retinal vasculitis can lead to retinal vascular occlusion and retinal artery occlusion. Retinal vascular occlusion is an obstruction of the veins or arteries of the retina, usually due to a thrombus or embolus, and can result in vision loss which may be severe and permanent. According to the plaintiffs, retinal vasculitis and retinal vascular occlusion are adverse events that are extremely rare in the absence of drug use. *See, e.g.*, filing 30 at 18.

Plaintiff Edith Harris received her first physician-prescribed Beovu injection on January 15, 2020. Case no. 4:21-cv-3013, filing 34 at 3. She received a second injection on February 17, 2020. Harris began experiencing severe vision problems in February 2020, and was diagnosed with retinal vascular occlusion in February 2020. Prior to using Beovu, Harris had been prescribed, and had used, other anti-vascular endothelial growth factor inhibitor drugs without any material side effects.

Plaintiff Judy Cohen received a physician-prescribed Beovu injection on January 14, 2020. Case no. 4:21-cv-3014, filing 32 at 3. She began developing severe vision problems in February 2020, and was diagnosed with retinal vascular occlusion in February 2020. Prior to using Beovu, Cohen had been prescribed, and had used, other anti-vascular endothelial growth factor inhibitor drugs without any material side effects.

Plaintiff Constance Sundell received her first physician-prescribed Beovu injection on January 21, 2020. Filing 30 at 3. She received a second injection on January 30, 2020. Sundell began experiencing severe vision problems in February 2020, and was diagnosed with bilateral retinal vascular occlusion in March. Prior to using Beovu, Sundell had been prescribed, and had used, other anti-vascular endothelial growth factor inhibitor drugs without any material side effects. Filing 30 at 3-4.

The plaintiffs alleged that the defendant began receiving post-marketing adverse event reports almost immediately after Beovu came on the market. *See, e.g.,* filing 30 at 18. The first such report was received on November 13, 2019, and concerned a report made by a physician of retinal vasculitis in a patient. The patient's condition was characterized as serious, and resulted in disability. The defendant received additional physician reports of adverse events following Beovu injections on November 14, December 11, and December 30. On January 3, 2020, the defendant received an additional six Beovu adverse event reports, and on January 23, received two more such reports. *See, e.g.,* filing 30 at 18-19. In February, the defendant received thirty-nine additional adverse event reports, fifteen of which were received on or before February 15. *See, e.g.,* filing 30 at 19.

According to the plaintiffs' allegations, the defendant continued to receive additional adverse event report in March, April, and May. The

plaintiffs alleged that although these physician-reported adverse events are based on well-established reporting principles, the number of reported events vastly underestimate the true number of adverse events actually occurring with Beovu users. Finally, the plaintiffs alleged that the defendant knew, but failed to disclose, that the data from its Phase III clinical trials used to obtain FDA approval demonstrated that trial participants injected with Beovu had a 2,312 percent increased risk of developing retinal vasculitis or retinal vascular occlusion compared to trial participants taking aflibercept, an approved anti-vascular endothelial growth factor inhibitor drug used as the trial's active control. *See, e.g.,* filing 30 at 21-23, 31. Further, the plaintiffs alleged that a study, funded and authored by the defendant, acknowledged a causal link between Beovu and retinal vasculitis. *See, e.g.,* filing 30 at 17-18. The defendant conceded that this study was published online on January 17, 2020. *See, e.g.,* filing 34 at 19.

III. DISCUSSION

1. STRICT LIABILITY FAILURE TO WARN CLAIM

The defendant posits several arguments for dismissal of the plaintiffs' failure to warn claims. First, the defendant asserts that the plaintiffs' claims are actually "fraud-on-the-FDA" claims that are preempted pursuant to *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). The Court disagrees. *Buckman*, unlike here, concerned a medical device—orthopedic bone screws—and the claim that the manufacturer had made fraudulent misrepresentations regarding the intended use of the screws in the course of obtaining approval to market its product for a use other than what had previously been approved. *Id.* at 343-46. In 1976, Congress passed the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act, which included an express pre-emption provision for medical devices, showing that

Congress intended enforcement of the MDA was exclusively with the Federal Government. *Id.* at 352. However, Congress did not enact a similar express pre-emption provision for prescription drugs. *Wyeth v. Levine*, 555 U.S. 555, 567 (2009). Accordingly, if the plaintiffs' claims are subject to pre-emption, it would be the result of impossibility—that is, it would be impossible for the defendant to comply with both state law and the pertinent federal requirements. *See id.* at 573.

A central premise of federal drug regulation is that the manufacturer, at all times, bears the responsibility for the content of its label. *Id.* at 570-71. The manufacture is "charged with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 571. In general, a manufacturer may only change a drug label after receiving FDA approval. *Id.* at 568. The regulations, however, have exceptions to the general rule, which authorize manufacturers to make certain changes to a drug label before receiving FDA approval. The "changes being effected" (CBE) regulations provides that the FDA may designate a "category of changes" whereby the holder of an approved application may begin distribution of its drug product upon the FDA's receipt of a supplement for a change. 21 C.F.R. § 314.70(c)(6).

Two such designated changes concern product labeling to reflect "newly acquired information" (1) to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under [21 C.F.R.] § 201.57(c)," and (2) to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." § 314.70(c)(6)(iii)(A) & (C). The standard referenced regarding evidence of a causal association provides, in pertinent part, that "labeling must be revised

to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." § 201.57(c)(6)(i).

According to the defendant, the plaintiffs failed to allege "newly acquired information" sufficient to trigger its duty to make label changes. *See, e.g.,* filing 34 at 13. The defendant argues that the articles and commentaries referenced in the plaintiffs' complaints regarding retinal vasculitis following a Beovu injection, with one exception, post-date the plaintiffs' exposures, and as such, cannot constitute information that would trigger a label change which would have benefited any of the plaintiffs. *See, e.g.,* filing 34 at 13-14. The one study referenced in the plaintiffs' complaints that pre-dates the plaintiffs' Beovu injections, according to the defendant, was published online on January 17, 2020, and is not newly acquired information, but instead, merely consists of a review of the data previously submitted to the FDA. *See, e.g.,* filing 34 at 19.

Similarly, the defendant argues that the allegations regarding physician-reported adverse events received by the defendant prior to the plaintiffs' Beovu injections also cannot constitute newly acquired information because the adverse event reports "do not represent new evidence of a different type or greater severity or frequency than previously included" in the defendant's submission to the FDA. Further, according to the defendant, adverse reports are merely "anecdotal descriptions of something that happened to a person" and do not purport to reach a causal association. *See, e.g.,* filing 34 at 17-18.

The Court is not persuaded by the defendant's assertions and arguments. First, notwithstanding the inapplicability of *Buckman*, and the fact that Beovu is not a medical device, the plaintiffs' complaints do not seek recovery for any sort of fraud perpetrated on the FDA in connection with

Beovu's approval. The allegations in the plaintiffs' complaints concern the defendant's purported failure to update its labeling as required by the CBE regulations, and the defendant's responsibility regarding the content of Beovu's label. *Wyeth*, 555 U.S. at 570-71. True, the plaintiffs alleged that the defendant knew that it failed to present accurate data in its submission to the FDA concerning adverse events in its Phase III clinical trials. *See* filing 30 at 13, 17-18, 22. However, taken in context, these allegations concern the defendant's state of mind—what the defendant knew and when the defendant knew it—more so that any claim of fraud on the FDA. Further, the plaintiffs specifically pled in their fraudulent misrepresentation claims that the defendant's misrepresentations at issue were communicated directly to the plaintiffs, as well as to the plaintiffs' healthcare providers—not the FDA. *See, e.g.*, filing 30 at 25.

The defendant, at all times, was responsible for the content of its labeling—both in crafting Beovu's label and ensuring its warnings remain adequate as long as Beovu was on the market. *Wyeth,* 555 U.S. at 570-71. The CBE regulations allowed the defendant to change Beovu's labeling to reflect newly acquired information to add or strengthen warnings, or adverse reaction for which there is evidence of a causal association. *Id.* at 568; § 314.70(c)(6)(iii)(A). The regulations required the defendant to include a warning "as soon as there is reasonable evidence of an association of a serious hazard" with Beovu. *See Wyeth*, 555 U.S. at 571; § 201.57(c)(6)(i). Further, newly acquired information is not the "narrow term" that the defendant suggests. Filing 34 at 9. It may include, but is not limited to, "new clinical studies, reports of adverse events, or new analyses of previously submitted data if the studies, events or analysis reveal risks of a different type or greater

severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 601.12(f)(6).

Here, the plaintiffs alleged that the defendant received ten adverse events reports prior to the plaintiffs' initial Beovu injections. *See, e.g.,* filing 30 at 18-19. The defendant received two more adverse event reports prior to Sundell's second injection, and before Harris' second injection, the defendant had received a total of twenty-seven adverse event reports. The plaintiffs also alleged that the defendant funded and authored a review of its clinical trials data that was published online prior to the plaintiffs' Beovu injections. *See, e.g.,* filing 34 at 19. This review concluded that there was a causal connection between Beovu injections and retinal vasculitis. *See, e.g.,* filing 30 at 17-18; filing 34 at 19. Newly acquired information is not limited to only new data, but includes the analysis of data previously submitted. *Wyeth,* 555 U.S. at 569.

The defendant argues that the plaintiffs have failed to allege that this previously submitted data was "reanalyzed," and as such, does not constitute newly acquired information. *See, e.g.,* filing 34 at 19. The Court observes that the plaintiffs alleged that this data was "reviewed," and a conclusion was reached regarding causation of retinal vasculitis which was not previously acknowledged by the defendant. *See, e.g.,* filing 30 at 17-18. "Reviewed" in this context, cannot be viewed as something other than a reanalysis of the existing data to reach a new conclusion.

Contrary to the defendant's arguments, this Court is unable to conclude that, as a matter of law, the physician-reported adverse event reports, as well as the reanalysis of the defendant's Phase III clinical trial data, does not constitute newly acquired information of events or analyses revealing risks different in type or of greater severity than previously reported to the FDA. The Court is also unable to conclude that, as a matter of law, even if the

physician-reported adverse events and reanalysis of the Phase III clinical trial data were newly acquired information, it was untimely information that failed to trigger the defendant's obligation to adequately warn of the risks and adverse events associated with Beovu injections.

Under Nebraska law, a manufacturer is subject to liability for failing to warn, or for failing to adequately warn, about a risk or hazard inherent in the way its product is designed that is related to intended uses, as well as the reasonably foreseeable uses, that may be made of the products it sells. *Freeman v. Hoffman-La Roche, Inc.,* 618 N.W.2d 827, 841 (Neb. 2000); *Ideus v. Teva Pharmaceuticals USA, Inc.,* 361 F.Supp.3d 938, 941 (D. Neb. 2019). A warning is adequate if it accurately and unambiguously conveys the scope and nature of the risk to the prescribing physician. *Id.* Expert medical testimony is generally required to determine whether the drug manufacturer's warning to the medical community is adequate because prescription drugs are likely to be complex medicines esoteric in formula and varied in effect. *Vallejo v. Amgen, Inc.*, 8:14-CV-50, 2014 WL 4922901, at *3 (D. Neb. Sept. 29, 2014).

Whether the defendant's responsibility to amend its label was triggered based on physician-reported adverse events, and the defendant's own reevaluation of its Phase III clinical trial data, at this point in the proceedings, is a question of fact for a jury to resolve, and a question that undoubtedly will require testimony and evidence from qualified experts. Further, whether the physician-reported adverse events demonstrate reasonable evidence of a causal association is also a finding that will likely require expert testimony and evidence.

Finally, the defendant asks the Court to conclude that the physician-reported adverse events do not constitute newly acquired information because the reports of retinal occlusions in Beovu patients were explicitly included in

the defendant's initial FDA-approved label for Beovu. *See, e.g.,* filing 34 at 17. According to the defendant, the October 2019 label for Beovu included a contraindication for active intraocular inflammation and various other warnings concerning potential vision injuries. *See, e.g.,* filing 30 at 3-4, 11-12. In support, the defendant asks the Court to access what it asserts is Beovu's 2019 label via a link to a website. The Court declines the defendant's request.

When deciding a motion to dismiss under Rule 12(b)(6), the Court is normally limited to considering the facts alleged in the complaint. If the Court considers matters outside the pleadings, the motion to dismiss must be converted to one for summary judgment. Fed. R. Civ. P. 12(d). However, the Court may consider materials that are necessarily embraced by the pleadings without converting the motion. *Mattes v. ABC Plastics, Inc.*, 323 F.3d 695, 697 n.4 (8th Cir. 2003). Documents necessarily embraced by the pleadings include those whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the pleading. *Ashanti v. City of Golden Valley*, 666 F.3d 1148, 1151 (8th Cir. 2012).

Even if no party questioned the authenticity of the defendant's label found at the referenced website, the Court would still have to determine, as a matter of law, whether the information in the label accurately and unambiguously conveyed the scope and nature of the risk to prescribing physicians. *Freeman,* 618 N.W.2d at 841; *Ideus,* 361 F.Supp.3d at 941. The Court would also have to make this determination without any testimony or evidence from qualified experts—something which the Court is unwilling, and ill-equipped, to do. *See Vallejo*, 2014 WL 4922901, at *3.

Here, the CBE regulations, viewed in the plaintiffs' favor, would permit the defendant to unilaterally strengthen Beovu's warning to comport with Nebraska law regarding the defendant's duty to adequately warn physicians

about risks associated with Beovu. It would not be impossible for the defendant to comply with both Nebraska law and federal regulations if it were necessary for it to update Beovu's label to warn of a serious hazard.

2. NEGLIGENCE

The defendant, in seeking dismissal of the plaintiffs' negligence claims, has not posited an argument separate or distinct from its arguments for dismissal of the plaintiffs' strict liability claims. There is, however, a distinction between a manufacturer's liability grounded on negligence, and liability grounded on strict liability. *Freeman*, 618 N.W.2d at 833. In a strict liability failure-to-warn claim, knowledge of the product's condition and associated risks is imputed to the manufacture, whereas in a negligence failure-to-warn claim the manufacturer's knowledge of the condition and risks must be proven. *See Bilotta v. Kelley Co., Inc.*, 346 N.W.2d 616, 622 (D. Minn. 1984). Here, the question is whether the defendant's failure to update its Beovu label was reasonable in view of the foreseeable risks of injury. *Freeman*, 618 N.W.2d at 833.

The allegations in the plaintiffs' complaints are sufficient to state a claim for relief regarding the defendant's negligent failure to warn. Those allegations, identified in detail above, include the physician-reported adverse events, the defendant's failure to present accurate adverse event data to the FDA, and the defendant's reevaluation of its Phase III clinical trial data showing a causal connection between Beovu injections and retinal vasculitis. Whether the defendant's failure to update its product label was reasonable in light of the risks, at this early stage of the proceedings, may not be determined by the Court as a matter of law.

3. Misrepresentation Claims

The elements for fraudulent misrepresentation under Nebraska law are: (1) a representation was made; (2) the representation was false; (3) when made, the representation was known to be false or made recklessly without knowledge of its truth and as a positive assertion; (4) it was made with the intention that the plaintiff should rely upon it; (5) the plaintiff did so rely on it; and (6) the plaintiff suffered damage as a result. *Freeman*, 618 N.W.2d at 844-45. Negligent misrepresentation has essentially the same elements as fraudulent misrepresentation, except for the defendant's mental state. *Nathan v. McDermott*, 945 N.W.2d 92, 109 (Neb. 2020). In a claim for negligent misrepresentation, a person may be liable even though acting honestly and in good faith if such person fails to exercise the degree of care required under the circumstances. *Lucky 7, LLC v. THT Realty, LLC,* 775 N.W.2d 671, 675 (Neb. 2009).

The defendant argues that the plaintiffs' amended complaints fail to comport with the heightened pleading standard in Fed. R. Civ. P. 9(b). *See, e.g.,* filing 34 at 20. Rule 9(b) standards are not quite as heightened as the defendant suggests. Pleading the particular circumstances constituting fraud is interpreted in harmony with the principles of notice pleading. *Drobnak v. Andersen Corp.*, 561 F.3d 778, 783 (8th Cir. 2009). Generally, a pleading alleging fraudulent or negligent misrepresentation must include the time, place, and contents of the false representations, the identity of the entity or source of the misrepresentation, and what was obtained or given up as a consequence of the false representation. *Id.* The heightened pleading standard for complaints of fraud or misrepresentations is intended to allow a quick and specific response to potentially damaging allegations. *Id.* However, Rule 9(b) provides that knowledge, intent, and other conditions of a defendant's mind

may be generally alleged. Further, facts constituting the misrepresentation that are peculiarly within the defendant's knowledge may be pled on information and belief. *Id.*

The defendant asserts that the plaintiffs have only alleged conclusory allegations of fraud, and have failed to plead facts showing their injuries resulted from reliance on the defendant's false statements. *See, e.g.,* filing 34 at 21. The Court disagrees. The fraud that the plaintiffs complain of is the defendant's alleged misrepresentation of the Phase III clinical trial data regarding the occurrence of retinal vasculitis associated with Beovu injections. *See, e.g.,* filing 34 at 26-38. The plaintiffs alleged that the defendant's own review of its Phase III clinical trial data concluded that the defendant had failed to reveal the risks of occlusive retinal vasculitis with significant vision loss associated with Beovu administration. *See*, *e.g.* filing 30 at 18. The plaintiffs also alleged, in great detail, the findings and conclusions of several studies, reviews, and case reports that identified a higher incidence of retinal vasculitis than what had been acknowledged by the defendant in its Phase III clinical study report, or included by the defendant in its product label. *See*, *e.g.* filing 30 at 9-16.

Further, the defendant's assertion that the plaintiffs failed to plead facts showing their reliance on a misrepresentation ignores that the plaintiffs alleged that they, as well as their physicians, all relied on the defendant's alleged misrepresentations and omissions. *See, e.g.,* filing 30 at 31. The learned intermediary doctrine is an exception to the general rule that a manufacturer or seller is subject to liability for failing to either warn or adequately warn a user about a risk or hazard inherent in the way a product is designed, or regarding a reasonably foreseeable use that may be made of its product. *Freeman*, 618 N.W.2d at 841. When prescription drugs are involved, the

doctrine provides, in essence, that a manufacturer's duty to warn is discharged when an adequate warning is provided to a patient's prescribing health-care provider. *Id.* Here, the plaintiffs' complaints alleged that their health-care providers relied on the misrepresentations in the defendant's product label, as well as the omissions of adverse event data, to assume that the defendant's product was safe. *See, e.g.,* filing 30 at 31-35.

IV. CONCLUSION

For the most part, the defendant's arguments fail to recognize that a motion to dismiss under Rule 12(b)(6) tests only the sufficiency of the allegations in the complaint, not the sufficiency of the evidence alleged in support of those allegations. *Stamm v. Cty. of Cheyenne, Neb.*, 326 F. Supp. 3d 832, 847 (D. Neb. 2018). The defendant's motion to dismiss must be denied in all respects for the reasons stated above.

IT IS ORDERED:

1. The defendant's motions to dismiss (case no. 4:21-cv-3013 filing 36, case no. 4:21-cv-3014 filing 34, case no. 8:21-cv-32 filing 33) are denied.

2. The defendant's motions for oral argument (case no. 4:21-cv-3013 filing 38, case no. 4:21-cv-3014 filing 36, case no. 8:21-cv-32 filing 35) are denied.

3. These matters are referred to the Magistrate Judge for case progression.

Dated this 8th day of September 2021.

BY THE COURT:

John M. Gerrard
United States District Judge